CHAPTER 2

2.0 PLANNING FOR AN HHRA

2.1 INTRODUCTION. The consistent standardized approach presented in this guidance document was devised to assure consistent treatment among sites. Numerous other resource materials, guidance documents, bulletins, memoranda, technical manuals, and books that address the general HHRA approach and scoping of site-specific data needs are available from EPA, other regulatory agencies, and scientific sources. A number of these resources are referenced in Appendix A. The generally accepted approach to performance of an HHRA is presented in RAGS (USEPA, 1989j), and a thorough understanding of the process is prerequisite to working within the USACE program. This guidance will not reiterate RAGS, but the following paragraphs will provide the USACE risk assessor and risk manager with the details necessary to focus investigations toward site closeout and to provide USACE policies and procedures on the HHRA process, along with "how to" and "where to find" knowledge for evaluating the scope, design, and conduct of a site-specific HHRA.

2.1.1 Purpose of the HHRA. The HHRA is an integral component of the PA/SI, RI/FS, RD/RA[11], and emergency response processes, serving multiple functions in decision-making:

- The HHRA provides an evaluation of the potential human health risks under baseline (i.e., no action) conditions.
- The HHRA helps determine the need for RA at the site.
- The HHRA provides a basis for determining RGs for chemicals in site media.
- The HHRA provides a basis for comparing different remedial alternatives.
- The HHRA provides a consistent and widely accepted methodology for assessing potential health risks, allowing for comparison of potential health risks between sites.

2.1.2 Objectives of the HHRA. The goal of the HHRA is to provide the necessary information to assist risk managers in making informed decisions. The HHRA provides important risk management input at various project phases, identifying receptors or resources to be protected, as well as limitations and uncertainty.

The HHRA should provide an objective, technical evaluation of the potential impacts posed by a site, with the risk characterization clearly presented and separate from any risk management considerations. Although risk assessment and risk management are separate activities, the risk assessor and risk manager need to work together at various stages throughout the project to define decision data needs. In the HHRA, the risk assessor needs to present scientific information in a clear, concise, and unbiased manner without considering how the scientific analysis might influence the regulatory or site-specific decision. The risk assessor is charged with:

- Generating a credible, objective, realistic, and scientifically balanced analysis.
- Presenting information on the problem, effects, exposure, and risk.
- Explaining confidence in each assessment by clearly delineating strengths, uncertainties (as well as an estimation of the effects of the uncertainties, both magnitude and direction), and assumptions, along with impacts of these factors (USEPA, 1995c).

The risk assessor does not make decisions on the acceptability of any risk level for protecting the receptors or selecting procedures for reducing risk. The HHRA is used by the risk manager, in conjunction with regulatory and policy considerations, to determine the appropriate response actions at the site.

2.1.3 Minimum Requirements. The provision for "minimum requirements" for the HHRA is an important

[11] As stated previously, this document assumes the processes involved in CERCLA and RCRA investigations to be equivalent. For the rest of these discussions, CERCLA terms only will be used. It may be assumed that the procedures are also appropriate for the equivalent RCRA phase.

concept. The risk assessor should identify particular minimum requirements for activities preceding and used in the HHRA to assure that critical factors are addressed. Early in the process of planning the HHRA, the risk assessor should also confer with the end users of the assessment to identify all factors that need to be addressed by the HHRA. The HHRA should be developed with its end uses in mind. Early interaction with risk managers and remedial designers is needed to obtain information on the risk management options likely to be considered if RA is required. This is not to infer that the HHRA should be "tailored" to specific remedial options, for that would compromise the objective nature of the assessment. However, if the risk manager or remedial designer needs certain information (for example, what depth of soil should be considered surface soils, given projected site use or exposure during remediation), the HHRA should provide the basis that will allow this question to be answered (within the appropriate boundaries of the HHRA).

2.1.4 Technical Requirements. The technical requirements of the HHRA should be considered early in the site planning and investigative phase to assure that appropriate information is gathered. It is important that the risk assessor be involved in the early planning stages of field investigations to develop the CSM, which will help guide the identification of site media to be sampled, and to assist in designing the chemical analytical scheme. The risk assessor should also assist in DQO development for performance-based methodology, design of the data review process, and performance of the data useability assessment. This will help assure that the best possible and most relevant data are available for use in the HHRA.

2.1.5 Technical Basis. Risk assessments developed for the various activities will have slightly different requirements, require a different scope, and will involve a different level of effort. However, the technical basis for performing the risk assessment is essentially the same. The main description of the risk assessment methodology is provided below, and discussions of all types of risk assessments are based upon this model. Therefore, the information presented is necessary to the understanding of other risk assessment applications. Each type of risk assessment is discussed in subsequent chapters.

The HHRA is one component of overall site investigation and remedial activities. It should be developed with a recognition of how it is supported by preceding and concurrent components of site activities, such as sampling and analysis for the ERA effort, and how it supports and shapes the subsequent components, such as RD. Although the HHRA is performed to achieve several specific objectives (describing current and future human health risks), it needs to be coordinated with other site activities (e.g., ERA) and needs to be responsive to other general site concerns (e.g., restoration, mitigation, litigation) and the resources (cost and schedule to be met) available.

The risk assessment process has been separated by convention into four subdisciplines: hazard identification, dose-response assessment, exposure assessment, and risk characterization (NRC, 1983 and NRC, 1994). Hazard identification is the process of determining whether exposure to an agent could cause an increase in the incidence of adverse health effects. The dose-response assessment evaluates the relationship between the dose of an agent and the probability of producing adverse effects. Exposure assessment evaluates the combination of chemical uptake and potential routes of exposure. Finally, risk characterization summarizes and interprets the information and evaluates the limitations and uncertainties in the risk estimates (NRC, 1994).

Risk assessments have different applications in different regulatory programs. This document discusses the application of risk assessment in the following phases of site activity:

- PA/SI.
- RI.
- FS activities, including development of remediation levels and comparative risk assessments associated with selected remedial options, followed by the evaluation of short term risks associated with the implementation of the selected remedial option.
- RD/RA activities, including potential need to further evaluate short-term risks for the purpose of designing/ implementing control measures.

- Assessment of residual risk after implementation of the selected remedial option.

2.1.6 Planning and Problem Identification. Planning and problem identification are critical to the success of the HHRA and its usefulness with respect to remediation planning. To assure that the scope of the HHRA is sufficient for making risk management decisions, the risk assessor must always be mindful of the question, "Do the data and approach support RMDM?"

In identifying data needs for the HHRA, the risk assessor must fully understand the customer goals and the regulatory program(s) driving the HTRW project execution. The concept of TPP is fully explained in EM 200-1-2 (USACE), which emphasizes the need for the data users (e.g., the risk assessor) to identify minimum data requirements for the tasks to be performed.[12] The concept of "minimum requirements" for the HHRA is important in that it identifies certain aspects for data collection activities preceding the risk assessment to assure that critical data gaps or factors are addressed.

The approaches and contents of the anticipated risk assessment should be explained or discussed in the project planning stage in unambiguous terms. An iterative, tiered approach to the risk assessment, beginning with screening techniques, is used to determine if a more comprehensive assessment is necessary. The nature of the HHRA depends on available information, the regulatory application of the risk information, and the resources available to perform the risk assessment. Informed use of reliable scientific information from many different sources is the central feature of the process (USEPA, 1995a,c). The TPP process should produce an outline for a site-specific HHRA that is credible, objective, realistic, and scientifically-balanced.

Throughout the planning discussions, the risk assessor should strive to point out potential setbacks, problems, or difficulties that may be encountered in a "real world" situation. When special circumstances (e.g., lack of data, extremely complex situations, resource limitations, statutory deadlines) preclude a full assessment, such circumstances should be explained and their impact on the risk assessment discussed. The risk assessor should also explain the minimum data quality considered to be acceptable, how non-detects will be treated, and how medium-specific data will be evaluated or compiled to derive or model the exposure point concentration in the risk assessment.[13]

2.2 PLANNING CONSIDERATIONS

2.2.1 Coordinating HHRA and ERA Planning. Planning for a HHRA should be conducted concurrently with that for an ERA in that these two efforts often have similar data needs. Data needs for the ERA, however, eventually focus on developing remedial alternatives that are protective of ecosystem components, while the HHRA focuses on developing remedial alternatives that are protective of a single species, humans.

Coordinated planning efforts for the HHRA and ERA efforts, particularly where there is to be an expedited cleanup, should include consideration of the following:

- Overlaps in information needs with regard to human and ecological food chain issues.

- Benefits of the cleanup and the effectiveness of presumptive remedies.

[12] The HTRW TPP process is a four-phased (Phase I through Phase IV) process that begins with the development of a site strategy and ends with the selection of data collection options. Throughout the process, USACE HTRW personnel of various disciplines and responsibilities (some of whom may assume multiple responsibilities) work closely together to identify data needs, develop data collection strategy, and propose data collection options for the customer. The HTRW data quality design process implements the EPA's DQO process, which is an iterative process applicable to all phases of the project life cycle.

[13] For example, if the RI data are skewed, it may be necessary to address site risk by evaluating hot spots separately. The risk assessor may wish to indicate this in the Work Plan, in order to characterize hot spot areas without delaying the assessment of risks for the non hot-spot areas.

- Ecological impacts from removal or remedial activities designed to protect human health.
- Identification of hot spots that may impact both human health and ecological receptors.
- Identification of the key assumptions and criteria common to the HHRA and ERA that may drive cleanup decisions and focus the decision making process.
- Identification of areas of greatest concern that may be addressed early as discrete tasks, thereby allowing priority to be given to those (removal/remedial) actions that achieve the greatest protection of the environment and human health for the capital (dollars) spent.
- Activities common to both the human health and ecological risk efforts that support DOD responsibilities as a Natural Resource Trustee or help coordinate between multiple Natural Resource Trustees where jurisdictions or responsibilities overlap.

2.2.2 Coordination with Natural Resource Trustees. In the risk planning process, on Superfund sites in particular, it is also important for the risk assessor, risk managers, the technical team, and decision makers to coordinate with natural resource trustees (e.g., DOD, the state, the National Oceanic and Atmospheric Administration [NOAA[14]], the U.S. Fish and Wildlife Service, the U.S. Forest Service, and the Bureau of Land Management) at the earliest possible stage. In this way, the trustee can be assured that potential environmental concerns are addressed, and conclusion of action may be expedited (USEPA, 1989g, 1989h, and 1989i). Coordination with natural resource trustee agencies such as NOAA provides for the exchange of ideas and issues to assure the technical adequacy of the RI/FS, to assure the protectiveness of the selected remedy for trust resources, and to provide for proper restoration and mitigation for injured resources. Coordination also allows DOD access to the trustees' specific skills, information, and experience. This interaction may occur through a variety of informal and formal forums, including but not limited to: preliminary scoping and drafting of work plans, review of final work plans and subsequent data, technical review committees, PM meetings, and public information meetings.

2.2.3 RAGS, Part D: Standardized Planning, Reporting, and Review of Superfund Risk Assessments. EPA Administrator, Carol Browner, called for an improvement in the transparency, clarity, consistency, and reasonableness of risk assessments (USEPA, 1995c). Subsequently, the October 1995 Superfund Administrative Reform #6A directed EPA to establish national criteria to plan report & review Superfund risk assessments. As a result, the *Risk Assessment Guidance for Superfund (RAGS): Volume I: Human Health Evaluation Manual; Part D, Standardized Planning, Reporting, and Review of Superfund Risk Assessments* (USEPA, 1998a) was developed. Additionally, EPA is developing standard approaches for lead risks, radionuclide risks, probabilistic analyses, and ecological evaluation that will be issued as revisions to RAGS Part D.

The RAGS Part D approach includes three basic elements: (1) Use of Standard Tools, (2) Continuous Involvement of EPA Risk Assessor, and (3) Electronic Data transfer to National Superfund Database. Brief descriptions of the three components follow:

2.2.3.1 Use of Standard Tools. The Standard Tools include a Technical Approach for Risk Assessment

[14] NOAA's Coastal Resource Coordination Branch (CRCB) works with EPA through all phases of the formal remedial process at Superfund waste sites. The CRCB acts for the Dept. of Commerce as trustee for natural resources such as anadromous and marine fish. Coastal Resource Coordinators (CRCs) and an advisory staff of environmental, marine, and fisheries biologists provide technical support and expertise to EPA, DOD, and other agencies during response and cleanup at coastal waste sites. The CRCs and supporting staff recommend appropriate environmental sampling, coordinate with other natural resource trustee agencies to build consensus on natural resource issues, and recommend appropriate clean-up levels. The CRCB works with EPA to gain cost-effective remedies that minimize residual resource injury without resorting to litigation. CRCs are in most EPA regions.

(TARA), Standard Tables, and Instructions for the Standard Tables. The TARA is a "road map" for incorporating continuous involvement of the EPA risk assessor throughout the CERCLA remedial process for a particular site. The TARA should be customized for each site-specific HHRA as appropriate. Electronic templates for the Standard Tables have been developed in Lotus and Excel for ease of use by risk assessors. For each site-specific risk assessment, EPA recommends the Standard Tables, related Worksheets, and supporting information first be prepared as Interim Deliverables for EPA risk assessor review, and should later be included in the Draft and Final BRAs.

Instructions for the Standard Tables have been prepared corresponding to each row and column on each Standard Table. The Instructions should be used to complete and/or review Standard Tables for each site-specific HHRA. Instructions, example tables, and blank tables are available for download at:
http://www.epa.gov/superfund/oerr/techres/ragsd/ragsd.html.

2.2.3.2 Continuous Involvement of EPA Risk Assessors. In this part of the document, the RPMs are instructed to use the EPA risk assessors for all CERCLA sites, from scoping through completion and periodic review of the RA. It is stated that early and continuous involvement by the EPA risk assessors should include scoping, work plan review, and site-specific customization of the TARA for each site to identify all risk-related requirements. It is also emphasized that EPA risk assessors support reasonable and consistent risk analysis and risk-based decision making.

2.2.3.3 Electronic Data Transfer to a National Superfund Database. Summary-level site-specific risk information will be stored in a National Superfund Database (CERCLIS 3) to provide data access and data management capabilities to all EPA staff. These risk-related summary data represent a subset of the data presented in the Standard Tables. The electronic versions of the Standard Tables (Lotus and Excel) are structured to be compatible with CERCLIS 3.

2.2.3.4 RAGS Part D Applicability. The approach contained in RAGS, Part D is intended for all CERCLA risk assessments. Its use is also encouraged in ongoing risk assessments to the extent it can efficiently be incorporated into the risk assessment process. Part D is also recommended for non-NPL sites, BRAC sites and RCRA sites when appropriate. Chapter 1 of RAGS Part D provides more detailed guidelines regarding the applicability of RAGS Part D as a function of site lead and site type. Each region will determine the site-specific applicability, but USACE risk assessors should consider its use on all HTRW projects.

2.2.4 The HTRW TPP Process. EM 200-1-2 (USACE) provides guidance on data collection programs and defines DQOs for HTRW sites. DQOs define the project's data needs, data use, number of samples required, the associated QA requirements (e.g., quantitation limits(QLs), blanks, split and duplicate samples, etc.), and level of confidence or acceptable data uncertainty for the requisite data. DQOs are generated at the final phase (Phase IV) of the TPP process after the customer has selected the preferred data collection program. The process includes evaluation of previously collected data, and assessment of the need for additional data to support the current or subsequent phases of the project. This coordinated TPP effort is designed to satisfy the customer goals, applicable regulatory requirements, and minimum technical data requirements for performing site investigations.

Throughout the process, USACE HTRW personnel of various disciplines and responsibilities work closely together to identify data needs, develop data collection strategy, and propose data collection options. The HTRW TPP process is consistent with the EPA's 7-Step DQO process, which is an iterative process applicable to all phases of the project life cycle. The DQO development process is considered to be a Total Quality Management tool (USEPA, 1989e). This is key to assuring successful planning and performance of the risk assessment.

Phases I through IV (described below) of the TPP process address site investigations methodically and should be incorporated throughout the entire HTRW project life cycle. Using this TPP process, the risk assessor will be able to define minimum information requirements for risk evaluations in support of site decisions.

2.2.4.1 Phase I - Develop Project Strategy. This phase of the TPP process involves identifying site decisions requirements and developing an approach to address these requirements. Site strategy is broadly defined in the

beginning of a project at this stage. As the project progresses into subsequent phases, the strategy is refined based on an improved understanding of the site. The risk assessor is crucial to the development of appropriate site strategy in this phase and the identification of data needs and the associated quality requirements to support risk management decisions. In this planning phase, site conditions are reviewed qualitatively, and a preliminary CSM is developed to help define the study elements for the current and subsequent TPP phases.

2.2.4.2 Phase II - Identify Potential Data Needs. This phase of the TPP process focuses on identifying data needs and minimum data quality requirements to support site decisions. Data users identify potential data needs and their respective proposed QA/QC requirements based on site background, regulatory information, and the customer's goal. At this phase, the compliance, remedy, and responsibility data users, who have specific data needs, present their data requirements along with the data needs identified by the risk assessor. The objective is to identify the data needs and quality requirements of all project team members.

2.2.4.3 Phase III - Identify Data Collection Options. This phase of the TPP process incorporates previously identified data needs and project constraints in designing a data acquisition approach. Various sampling approaches can be used, ranging from purposive (judgmental or biased) to representative (random) sampling methods. Additionally, various analytical schemes may be used such as screening or definitive data. This phase of TPP also involves identifying the optimum sampling/data collection scheme so as to minimize mobilization, field sampling, and demobilization efforts and costs. The objective of Phase III is to identify options (preferably two or three options, out of which one is an optimum option) for presentation to the customer in Phase IV.

2.2.4.4 Phase IV - Select Data Collection Options and Assign DQOs. This is the most important phase of the TPP process because this is where the data collection option is selected. To properly execute Phase IV, the proposed options should be clearly explained and characterized. The discussion should include data uncertainties, cost/benefits, schedule, and other constraints.

The product of this phase of the TPP process is the Statement/Scope of Work (SOW) for USACE work acquisition (either internal or the architectural-engineering contractor), a detailed cost estimate (or Independent Government Estimate) for the selected option, and DQOs for the data collection program. The DQOs explain the objectives of the data gathering activity, the data type/location, data collection and analytical scheme, the required QLs, rationale for requiring certain data quantity and quality, and how the data are to be used in making site decisions. Caution should be taken at this point about the integration and coordination between the HHRA and ERA as to how they influence DQOs. ERAs may require lower media-specific QLs than HHRAs for certain COPCs (Contaminants of Potential Ecological Concern for ERAs). The ultimate DQOs should be the lower of either for dual purpose samples, or the appropriate concentration for specific purpose samples.

2.3 ESTABLISHING THE LEVEL OF EFFORT

An important part of planning for a HHRA is determining the appropriate level of effort necessary to provide the required information. As sites will vary in complexity, so will the HHRA. Some of the site-specific factors affecting the level of effort include the following:

- The number and identity of the chemicals present.
- ARARs, to-be-considered (TBC) criteria, and applicable toxicity data.
- Reasonable future site use.
- The number and complexity of complete exposure pathways and the need for fate and transport modeling to establish exposure point concentrations.
- The required QLs based on screening values and the receptor populations.
- Quality and quantity of existing analytical data.

The following sections present requirements for planning risk assessment scopes of work for the various phases of response. In addition to the evaluation of human health risks, evaluation of the potential risks to ecological receptors should be considered as well during the

planning process, as duplication of effort needs to be avoided. See the companion to this manual, EM 200-1-4, *Risk Assessment Handbook, Volume II: Environmental Evaluation* (USACE) for considerations necessary for scoping an ERA. The following discussions will help guide your data needs assessment but are not intended to be all-encompassing. Data needs depend on the complexity of the site, amount of useable data already in existence, and site-specific receptors.

2.3.1 Preliminary Risk Screening; PA/SI. This section focuses on data needs for the preliminary risk screening in the site evaluation (site assessment) phase in CERCLA and RCRA. Other HTRW site assessments, although not specifically covered under these statutes, are expected to be functionally equivalent.

2.3.1.1 Review of Existing Site Information. Before the data needs for the PA/SI are conceptualized, the risk assessor should carefully review all site background information. The data quality used to produce reports or for proposed placement on the NPL (if available) should be evaluated for this phase of execution, along with a determination of whether additional data are needed. This phase of investigation usually has little existing quantitative information available. The purpose of this review is to gain a good understanding on the following issues:

- Regulatory concerns or site problems relating to human health to aid in preliminary identification of significant exposure pathways (source, migration/transport mechanism, exposure routes, and receptors).[15]

- Physical characteristics and demographics of the site which may help define possible pathways of exposure.

- Operational history with regard to site waste types, probability of occurrence, and location of source areas.

This information will be valuable to begin to conceptualize possible pathways of exposure and in determining data needs to support the risk screening analysis.

2.3.1.2 CSM.

2.3.1.2.1 Data needed for the risk screening analysis should be based on a preliminary CSM which is developed in the absence of extensive site information. If there are data available from a previous study, they should be evaluated for useability in the risk screening, prior to defining additional or supplemental data needs required in the PA/SI. The CSM helps identify and visually organize potential exposure pathways and receptors and identifies those pathways which could be complete (significant or insignificant) or incomplete, for the purpose of the data needs determination. The elements of a CSM are:

- Source of contamination (ground water, surface water, soil/sediment, and air).

- Potential release mechanism.

- Migration pathways.

- Potential receptors.

- Major exposure routes (e.g., ingestion, inhalation, dermal contact).

2.3.1.2.2 The risk assessor should begin to conceptualize the data needs associated with each of the aspects of the CSM that would support the screening risk evaluation. For example, it may be determined that limited judgmental sampling data can be used to conservatively define source concentrations for direct contact exposure point concentrations. A limited number of monitoring wells may be sufficient to evaluate the ingestion route for ground water. Additionally, the physical characteristics as well as the demographics of the site are also helpful in the evaluation of potential receptors and therefore complete pathways to be evaluated in the risk screening analysis. All parts of the CSM must be

[15] In addition to the regulatory actions or concerns, the risk assessor should also review any draft or final public health advisories, e.g., the ATSDR health consultations/advisories, state health/conservation advisories on indigenous food sources, etc. The data may be needed to accept or reject such advisories or concerns. USACHPPM should be consulted on all these public health matters.

examined to ascertain that each element of potentially complete exposure pathways has existing data that adequately support each component of the risk screening analysis.

2.3.1.2.3 Examples of general chemical data needs according to source/route/receptor for use in assessing potential exposure pathways for the risk screening are:

- Surface soil (incidental ingestion/dermal contact and inhalation of volatile organic compounds [VOCs] and airborne particles).
- Surface water (incidental ingestion/dermal contact).
- Ground water (ingestion, dermal contact, and inhalation of volatilized ground water contaminants due to indoor use of ground water).

2.3.1.3 Identification of Data Gaps. Once all existing data has been evaluated relative to the preliminary CSM, the risk assessor can determine what data are required to assure that the subsequent investigation can evaluate risks due to all pathways identified as complete and significant. Limited sampling of media expected to be impacted by site operations can provide adequate information to eliminate a site from further study. It is important to remember that this phase of investigation does not attempt to determine nature and extent of contamination, nor to determine the magnitude of any potential risks present. The intent is to determine whether the site poses no significant risk, and may be proposed for NFA, or must be evaluated further. This aspect is further clarified in Section 2.4.1.5.

2.3.1.4 DQOs: Determining Data Needs and Documentation. The level of effort is limited in this type of assessment as is the amount of data needed to support the screening.

2.3.1.4.1 In this step the general data needs defined during conceptualization are formalized as data requirements for each media type, specifying location of sampling, depth of samples required, chemical analysis requirements and corresponding DLs and QLs (based on health-based screening levels for comparison), confidence, and in some cases number of samples. The risk assessor may consider a weight-of-evidence approach when specifying data requirements and subsequently evaluating the collected data to aid in making informed site decisions at this stage of the HTRW response process. This is justifiable if a weight-of-evidence approach is used to support the evaluation and recommendation. For example, the topography, visual observations, history of spills, runoff pattern, and the analytical results of purposive sampling would be sufficient, as a whole, to support the argument whether contamination of a medium is likely or unlikely.

2.3.1.4.2 For chemical data, however, the level of confidence will be dependent on the QA/QC, sampling method, sample handling/preservation method, analysis method, and variability of the chemical concentrations in the medium that was sampled. Reference the following EMs for the requirements for the USACE chemistry program: EM 200-1-1, *Validation of Analytical Chemistry Laboratories* (USACE); EM 200-1-3, *Requirements for the Preparation of Sampling and Analysis Plans* (USACE); and EM 200-1-6, *Chemical Quality Assurance for HTRW Projects* (USACE)[16]. The following factors should be considered in this planning activity in order to reduce uncertainties:

- Analytical methods should be clearly stated that identify the method DL and the QL. At a minimum, the QL must be less than the action level to prove reliable detections.
- Level of QA - Depending on data use, the level of QA for PA/SI can be field screening (i.e. screening-level data) to assist identifying sampling locations, presence or absence of contaminants with some confirmational analyses, or confirmational analyses of chemical identification and quantification, e.g., gas chromatography/mass spectrometry method (i.e., definitive data).
- QA/QC samples - Soil or sediment samples should have field duplicates, laboratory control samples, matrix spikes, and matrix spike duplicate samples. Water samples should have field duplicates. In addition, samples for the analyses of volatile and semivolatile organic chemicals should be checked for surrogate recovery. Laboratory blanks should also

[16] EM 200-1-1 and EM 200-1-3 are currently in revision and should be published in FY99.

be analyzed to check for the presence of potential laboratory contaminants.

- Data variability - Detection of hot spots may not be the objective of the sampling program under PA/SI. The number of samples required to represent the level of contamination with a predetermined level of confidence will depend on the uniformity or homogeneity of the contamination. This information can only be obtained via historical documentation or previous sampling events.

2.3.1.5 Risk Screening. The essence of the screening-level assessment is to determine if the site may be eliminated from further concern or requires further study, based on past releases, ARARs, and/or human health impacts. The project study elements may include current and future land use and the population characteristics, based on the evaluation of the preliminary CSM. However, this is a preliminary screening, and is intended to be a conservative assessment of potential site risks. Usually, the risk screening employs the highest detected concentrations and compares them with health-based screening levels, appropriate for the current and projected future land use of the site. Generally, exceedance of these conservative values is only an indication that further study may be required, and does not indicate that risks are significant, or that they even exist. See Chapter 6 for a complete discussion of risk management issues appropriate at this phase of investigation.

2.3.1.6 Reporting Requirements. The following elements should be clearly presented in the PA/SI Report:

- Preliminary CSM, adjusted according to any new information identified during the field investigation.
- DQOs and an evaluation of whether or not they were met.
- The comparative risk analysis (the evaluation of maximum detected values relative to health-based screening levels).
- Discussion of all uncertainties and their potential impact on the results of the risk screen.

2.3.2 HHRA; RI. The sections below focus on HTRW scoping for the baseline HHRA[17] performed in the RI. The purpose of the BRA is to estimate the degree of risk associated with the site to human receptors in order for an informed risk management decision to be made regarding future actions. Generally, if the baseline risk is acceptable, there should be little basis for the FS or RD/RA.

2.3.2.1 Review of Existing Data. At this project phase, the risk assessor should have some understanding of the site background and descriptions of site characteristics from the review of the preliminary (PA/SI) data, contained in the Federal Facility Docket or pertinent project files. This information will be useful in focusing the data needs required to prepare the BRA. Before the data needs are determined, it is recommended that the risk assessor carefully review all site background information and site assessment reports, available state and/or EPA reports, removal action information (if applicable), SI worksheets, notes, or photos, etc. These studies, reports, and photos help the risk assessor begin to focus on aspects of the site which will require evaluation in the RI under the BRA.

2.3.2.1.1 Historical data collected for purposes other than BRAs may be available from previous investigations, facility records, permit applications, or other sources. However, historical data sets may be limited by the lack of information on laboratory and QA/QC procedures, or are obtained from the wrong media and wrong location for use in the BRA. Data from historical sources may or may not be appropriate to use in the quantitative BRA and should be reviewed for useability. When evaluating historical or purposively collected data, a number of factors need to be evaluated.

2.3.2.1.2 The review focuses on the following issues:

- Regulatory concerns (or newly identified concerns) relating to specific receptors, COPCs, and the

[17] For the purposes of this text, Baseline HHRA and BRA can be used interchangeably. BRA will be used here to avoid confusion with established EPA guidance for HHRA (USEPA, 1989j). It is understood that the evaluation of potential environmental risks, or ERA, is an integral part of the BRA.

exposure pathways of concern, as well as those pathways exceeding health-based screening levels in the PA/SI screening-level HHRA.

- Source areas which have been identified in previous studies and the need for further quantification to evaluate extent of contamination and risks.

- Spatial relationships of pathways, and the need for segregation as EUs or OUs to properly evaluate risks to a number of receptor groups.

- Possible transport pathways and available temporal data, chemical/physical data describing degradation, attenuation, or migration of chemicals in the environment.

- All possible current site receptors, including those that may be considered sensitive, to begin grouping by classification: agricultural, residential, etc.

2.3.2.2 CSM. The CSM is the basis for development of the level of effort for the risk assessment and the DQOs that will be defined in the SOW. The CSM presents contaminant sources, release mechanisms, transport media, exposure pathways, exposure points, and receptors for current and future land uses. The CSM helps organize and identify those pathways which are complete (significant or insignificant) and incomplete. The risk assessor should review site data and information collected in the previous project phases (PA/SI) to refine the CSM. The information should be able to assist the risk assessor in developing a more definitive CSM or multiple CSMs if there are multiple OUs. A CSM for ecological receptors should be developed concurrently with the CSM. EM 200-1-4, Vol. II (USACE) describes this process. The CSM for the BRA should help define and organize by pathway:

- Classes of COPCs (information concerning the source characteristics, medium contamination, and background chemicals is needed to identify COPCs).

- Potential target media (ground water, surface water, soil/sediment, and air).

- Potential receptors exposed to the target media.

- Major exposure routes or pathways of concern (e.g., direct contact resulting in soil or sediment ingestion or dermal absorption of contaminants in the media, consumption of food chain crops or species, ground water ingestion, and inhalation of contaminants in ambient air).

- Migration and transport potential of site chemicals from the source, including the effect of existing institutional controls or removal actions (e.g., ground water capture well systems).

- Potential secondary sources of contaminants, and their release/transport mechanism(s).

2.3.2.3 PRG Development. PRGs should be prepared or obtained to assist in planning. PRG values will be used in establishment of adequate QLs for the analytical scheme. In order to characterize risks, QLs must be lower than the PRG value used. Values developed by EPA Regions such as Region 3 Risk-Based Concentrations (RBCs), or Region 9 PRGs may be used for direct comparison, or the risk assessor may develop PRGs using default values for the appropriate land uses for the site using methods described in RAGS, Part B (USEPA, 1991d). Additionally, to evaluate inter-media extrapolation, methods outlined in *Soil Screening Guidance: User's Guide* (USEPA, 1996b) and *Soil Screening Guidance: Technical Background Document* (USEPA, 1996a) may be used.

2.3.2.4 Identification of Data Needs. During the review of background information, the risk assessor will likely notice that there is limited data and information available from previous investigations, and that additional data must be collected in the RI to support a BRA. The technical team should note data gaps that exist and will need to be considered in the development of the data collection strategy for the RI. Common data gaps may include insufficient characterization of nature and extent of contamination to adequately describe an exposure pathway, insufficient background characterization, and insufficient sample number to determine a 95% Upper Confidence Limit (UCL) of the mean concentration for an exposure area.

The data needs for an RI focus on addressing the nature and extent of contamination, potential migration, and possible receptors available to complete the exposure

pathways. Guided by the CSM, different types of data may be needed to address requirements and objectives of the BRA.

- Data or information in support of determining current and future land use and population characteristics.

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- Data to support fate and transport modeling/calculations (total organic carbon, grain size, porosity, processed meteorological data, etc.).

- Data to conduct qualitative and/or quantitative evaluation of uncertainties in the risk assessment (mean, maximum, minimum, or the entire distribution of values for key parameters identified by a sensitivity analysis).

- Data to support qualitative assessment of potential receptors and populations (census information, postal-carrier route information/DataMap®, etc.).

- Toxicity data to assess risk or hazard. Where critical toxicity values are not available from EPA, the appropriate DOD Toxicology and Research Program offices may be consulted (e.g., USACHPPM Toxicology Directorate at: http:// chppm-www.apgea.army.mil/tox/program.htm then contact the Health Effects Research Program Manager; or contact the Air Force Research Laboratory, Human Effectiveness Directorate, Operational Toxicology Division, at: http://voyager.wpafb.af.mil or (937) 255-5150 x3105).

- Representative data for evaluating the nature and extent of source and pathways, with appropriate confidence for intended data uses, and background chemical concentrations.

2.3.2.5 DQOs. The quality of a BRA is directly dependent upon the quality of the chemical data applied. Regardless of how well other components of the BRA are performed, if the quality of the data is poor or the data do not accurately reflect the site contamination or the types of exposures assessed, the BRA will not provide an adequate description of potential health effects posed by the site. Therefore, it is imperative that the types of data scoped for use in the assessment be carefully planned.

2.3.2.5.1 Planning for appropriate data acquisition is an important step in obtaining data of the necessary quality. During this planning stage, appropriate location, numbers, and types of samples, DLs and QLs, and analytical requirements can be specified as part of the DQO process. These and other specific minimum requirements for BRA data should be specified prior to data collection by the technical team in early stages of site planning or scoping. Once available, a thorough review of the resultant data is needed to assure that the DQOs have been met (see section 4.2). This further assures that the most appropriate information is used in the BRA.

2.3.2.5.2 The risk assessor should begin to document data needed, identifying data types, location, quantity, and quality requirements. Chemical data to be collected should be identified with the appropriate QA/QC requirements. See *Guidance for Data Useability in Risk Assessment (Part A)* (USEPA, 1992h). In addition, the level of confidence (maximum error rate) required of the sample results should be set, after considering the potential variability of the sample results in a given matrix and potential laboratory/sampling handling errors. For nonchemical types of data, the QA requirements will be established on a case-by-case basis. At a minimum, the source of nonchemical data and an assessment of their reliability and representativeness for use at the site should be documented.

2.3.2.5.3 The analytical methods applied to BRA data collection should be specified as part of the minimum requirements prior to the data collection. Once data results are available, the analytical methods used and DLs and QLs attained should be reexamined to identify any deviations from the minimum requirements, and the impact of that deviation upon data useability.

2.3.2.5.4 Three broad types of analyses are available, each having a different potential use in a BRA:

- Field screening data, such as those collected with direct-reading or field instruments (photoionization detectors, combustible gas indicators, or field chemistry tests). Because of the uncertainty associated with these methods (due to lack of stringent QA/QC protocols), these data are best used

qualitatively or in conjunction with verified results by more reliable methods unless the method can demonstrate equivalency with a proven method.

- Field laboratory analyses, such as those obtained from a mobile onsite laboratory. These data can be used in a BRA if appropriate QA/QC procedures have been followed and the data are of good quality, as determined by the data evaluation process.

- Definitive data. These data are appropriate for inclusion in a BRA if appropriate QA/QC procedures have been followed and the data are of good quality, as determined by the data evaluation process.

2.3.2.5.5 Several different laboratory analytical protocols are available, varying in the instrumentation, the level of QA/QC, sensitivity, QLs, and other factors. EM 200-1-3 (USACE) presents summaries of common analytical methods and identifies the instrumentation and DLs/QLs for different analytes. This resource should be consulted when choosing analytical methods to quantitate data for use in the BRA.

2.3.2.5.6 Two analytical protocols that are commonly applied to environmental sampling are the EPA's SW-846 protocol and the Contract Laboratory Program protocol. To give the USACE programs the greatest flexibility in the execution of its projects, the SW-846 methods, as published by EPA, are generally the methods employed for the analytical testing of environmental samples. These methods are flexible and can be readily adapted to individual project-specific requirements (USACE, 1994b).

2.3.2.5.7 The minimum requirements for planned BRA data collection should also specify the QLs to be attained in the chemical analyses. The limits should be low enough to enable quantitation of chemicals below concentrations of potential health concern. QLs are generally specified by the analytical method; however, deviations from planned QLs can occur as a result of matrix interferences, high chemical concentrations, laboratory variations, and other factors.

2.3.2.5.8 When selecting QLs the risk assessor and project chemist should consider that EPA risk assessment methodology specifies that one half the sample QL should be used as the proxy chemical concentration if there is reason to believe that the chemical may be present on the site. Appropriate QLs can be determined by an evaluation of health-based screening levels for site chemicals (see paragraph 2.4.2.3).

2.3.2.5.9 Data quality. For chemical data, the level of confidence will be dependent on the experience and the ability of the laboratory to be able to deliver quality data, associated QA/QC, and variability of the chemical concentrations in the medium that was sampled. Coordination between the risk assessor and project chemist/data reviewer is recommended in order to design the sample collection program which is most likely to produce sample results with an acceptable level of confidence, considering such factors as laboratory QA/QC, level of QA required for the data, QA/QC samples, and data variability. Sensitivity requirements should be identified in this scoping phase so that the data collection program will minimize the degree of uncertainty.

2.3.2.5.10 The output of the data planning discussed above should be a SOW section and/or data needs worksheets. The purpose of documentation, as well as communication with the other team members, is to avoid potential misuse of data or the risk assessment results, making sure that the selected data collection option meets the users' and decision-makers' needs. In particular, the risk assessor should explain the minimum data quality considered to be acceptable, how nondetects are treated, and how medium-specific data are evaluated or compiled to derive/model the exposure point concentration in the risk assessment. If a health assessment, health survey, or epidemiological study is to be performed by the ATSDR, the risk assessor should (in coordination with USACHPPM for Army IRP and FUDS projects) indicate in the summary or outline how the data are to be used, evaluated, or interpreted.

2.3.2.6 Reporting Requirements. The risk assessor should define the minimum requirements associated with each of the following elements. Specification of these project study elements and minimum requirements should be recorded in the SOW. Defining minimum requirements will also add more specificity to the CSM

development, allowing for easier determination of the data needs.

- Data evaluation - COPC selection, defining site-related chemicals, and nature and extent of source areas.
- Exposure assessment - pathway evaluation, fate and transport of contamination, exposure point concentration, and intake assessment.
- Toxicity assessment - determination of toxicity values.
- Risk characterization - calculation of risks.
- Uncertainty analysis - quantitative and qualitative documentation of uncertainties associated with each phase of the study.

2.3.3 Risk-Based Analysis of Remedial Alternatives; FS. The scoping requirements for the FS focus on evaluating the potential alternatives for their effectiveness in reducing the baseline site risk. Data are needed to assess any short-term or long-term risks (if the RA lasts a duration in excess of 7 years).[18] It should be noted that many sites are required to have the RI and FS to be conducted simultaneously. Therefore the preparatory steps for conceptualizing data needs between RI and FS are comparable and will not be reiterated here.

Risk aspects of the FS are three-fold:

- Development of site-specific cleanup levels for screening remedial alternatives and consideration for adoption as RAOs.
- Evaluation of potential remedial alternatives for their abilities to meet RAOs.
- Assessment of the fate and transport mechanisms of any potential release or discharge of the media being remediated or treatment byproducts/ residues.

In addition to evaluating the alternatives for "protectiveness" of human health and the environment, the risk-based evaluation of remedial alternatives must consider risk and toxicity reduction, interruption of the exposure pathway(s) shown to pose the principal threat in the BRA, and the post-remediation (residual) risk.

2.3.3.1 Review of Existing Data. At this project phase, the risk assessor and the project team should have a good understanding of the nature and extent of contamination. In addition, they will also have a good understanding of the site strategy and customer's goals and concept of closeout. In reviewing the background information, the risk assessor should note the AOCs requiring remediation, and the location of these areas relative to future as well as current onsite and offsite populations. Census projections and other demographic information should be reviewed. Locations of sensitive populations (nursing homes, nursery schools, etc.) should also be noted. The background information review may also identify issues of concern, for example:

- Previous or newly identified regulatory concerns relating to residual risks (risk remaining upon completion of selected remedies and/or proposed removal actions).
- Project status with respect to decision path leading to site closeout if the selected alternative is not effective or fully implemented.
- Customer's goals and objectives, plan of action, budget/time constraints for RD/RA, removal actions, and the 5-year review, if applicable.

2.3.3.2 CSM. The refined CSM developed for the BRA will be reevaluated in the FS scoping phase to account for pathways which reflect post-remediation conditions as well as pathways that may become available during remediation. Two CSMs may be developed for each remedial alternative: (1) the CSM during remediation; and (2) the CSM for the site after remediation has been completed. The former is used to guide data needs to assess short-term risks (or long-term risks if the period of remediation is in excess of 7 years); and the latter, to guide data needs for the degree of risk reduction or the post-remediation risk. The exposure pathways of concern for the short-term risk CSM are primarily air (fugitive dusts or VOC emissions) and discharge of treated effluent

[18] The 7-year period has been suggested by EPA as the point of departure between short-term (subchronic) and long-term (chronic) risks.

to ground water/surface water. It should be noted that neither of these evaluations requires an assessment of the net environmental benefit if offsite treatment/disposal is the alternative to be evaluated.[19] Therefore, the risk evaluations under FS are limited to impacts on human receptors who reside onsite or near the facility, and residual risks to receptors after implementation of the alternative. It should be noted that control measures required to mitigate short-term risks associated with remediation should be conducted in the RD/RA stage.

2.3.3.3 Identification of Data Gaps. It should be noted that this stage of HTRW project planning should focus primarily on the two questions: "What is the degree of risk reduction offered by the remedial alternative?" and "What are the potential short-term and long-term risks (if applicable) associated with implementation of the alternative?" Guided by the CSMs, data may be needed for all or any one of the following risk assessment tasks to assist in the selection of a remedial alternative:

- Data to support fate and transport modeling (e.g., grain size and processed meteorological data);
- Data to conduct qualitative and/or quantitative evaluation of uncertainties in the risk assessment (mean, maximum, minimum, or the entire distribution of values for key parameters identified by a sensitivity analysis). It should be noted that this level of effort is generally not required except for onsite incineration.
- Data to assess risk or hazard to receptors (rate, concentration, chemical identity, and toxicity) of emissions or treatment products/residues which may be released during remediation.
- Data on the treatment byproducts and residues.

2.3.3.4 DQOs. This step defines the specific data requirements according to potential exposure pathways (ingestion of and dermal contact with ground water, inhalation of airborne contaminants, etc.) which were identified as data gaps in the previous step. SOW sections should be prepared to document required data types, locations, and quality requirements. Chemical data to be collected should be identified with the appropriate QA/QC requirements. In addition, the level of confidence (maximum error rate) of the sample results should be defined, after considering the potential variability of the sample results in a given matrix and potential laboratory/sampling handling errors. The emission or discharge data may be obtained by modeling or from the results of a performance test of the full-size model or a pilot-scale model.

2.3.3.5 Risk Calculations: RAOs and RGs. RAOs consist of medium-specific RGs, modified from PRGs during or after the BRA, to assure protectiveness of human health and the environment. The final modification to the PRGs calculates allowable media concentrations from the acceptable risk levels determined through the risk management process. RAOs should be expressed as both a contaminant level and an exposure route, as protectiveness may be achieved by either reducing the contaminant level, or by reducing or eliminating exposure. Coordination of this process with the RAOs/RGs developed during the ERA is critical to assure that the selected remedy is protective of both human and ecological receptors.

2.3.3.6 Reporting Requirements. The requirements to be reported in the FS are summarized and identified below:

- Development of RGs, presented in the RAOs section.
- Assessment of RAO protectiveness, given the acceptable risk range and uncertainties in deriving the RGs, background concentrations, and the analytical DLs. Presented as part of the screening of alternatives section.
- Assessment of long-term effectiveness/residual risk to human health and the environment (evaluate if risk reduction afforded by the proposed remedial alternatives is effective). Presented in the detailed analysis of alternatives section.

[19] EPA has implemented an off-site policy (USEPA, 1993a) requiring the facility receiving environmental debris or media for treatment or disposal be either in compliance with RCRA Subtitle C or under a scheduled compliance action or corrective action.

- Assessment of short-term effectiveness (evaluate if the proposed remedial options pose unacceptable short-term risks to humans onsite and offsite during the RA. Presented in the detailed analysis of alternatives section.

2.3.4 Short-Term Risks Associated With Construction. This section focuses on HTRW data scoping for the evaluation of control measures needed to mitigate short-term risks posed by construction of CERCLA removals or RAs. To meet the risk assessment or evaluation data needs, the risk assessor should coordinate with the PM, as well as other data users to identify the remedy aspects which require risk evaluation in this phase.

As a screening or comparative risk analysis has already been performed in the RI/FS project phase (or an EE/CA for a non time-critical removal action), performance of risk assessment tasks in this phase is generally limited in scope (unless there is a need for a more detailed risk assessment because the construction is likely to result in a significant release of site COCs). If this is the case, information from previously performed risk analyses should be reviewed and additional data needs identified as required. Risk assessment of removal actions or construction of the selected remedial alternative should generally follow procedures and data requirements described in RAGS Part C (USEPA, 1991e).

When evaluating data needs and their quality/quantity, consideration should be given for completing the evaluation in a timely manner. Striking a balance between the desire for site-specific/treatability data and assumed data (data from other sites) for use in the evaluation is the key aspect in this project planning stage. Other areas for project planning that may require coordination between the risk assessor and other project team members (e.g., the health and safety specialist) are:

- Short-term impact of the remedial alternatives on site environment (i.e. acute risks to ecological receptors or habitat destruction, or risks to surrounding human populations and/or on-site remedial workers).

- Risk of accidents during construction (physical hazards, explosions, spills, etc.).

- Risk communications (public perception and understanding of risks from the alternatives).

- Other risk management considerations or criteria (e.g. cost, schedule, operations and maintenance/engineering and operational flexibilities, etc.).

2.3.4.1 Review of Existing Data. The information developed in the FS in conceptualizing data needs to assess the short-term risks can be used to develop or revise the site strategy. It is recommended that the project team carefully review all site background information, RI and FS reports, and any pertinent field tests or studies.

Through qualitative or quantitative risk assessment or analyses, a determination will be made as to whether or not additional controls are needed to address risks during remediation or the residual risks. If the assessment indicates any unacceptable potential risks, the decision will focus on: (1) whether the selected remedy can be implemented under the design and operation plans without posing an unacceptable short-term risk or residual risk; (2) the need for removal actions to reduce the threat of human health risks or expedite/enhance site remediation; and (3) control measures (operational or engineering) to mitigate site risks and to assure compliance with ARARs and TBC requirements. Therefore, specific decisions associated with this executable project phase may include all or any combination of the following:

- Determine whether the selected remedial or removal actions are likely to comply with Federal and State ARARs or TBC health-based criteria required by the agencies regarding short-term risks.

- Determine if additional control measures are required to be designed and implemented to mitigate or reduce short-term risks (or if new remedies should be recommended to replace the selected remedies).

- Determine if removal actions are needed to mitigate imminent threat to human health and environment.

- Determine if the selected removal actions are consistent with the final site remedy (if such remedy is reasonably expected).

2.3.4.2 CSM. Data needed for evaluation of controls to reduce short-term risks associated with remediation should be based on the CSM developed in the FS, focusing on the potential impact of the remedy to receptors identified, and the effect of control measures. The data needed may be nonchemical in nature, e.g., engineering design parameters to reduce, remove, or change the physical/chemical nature of the emission, effluent discharge, or residues. The sources of these data may be the remediation vendors/contractor, EPA's literature (e.g., feasibility studies under the Superfund Innovative Technology Evaluation [SITE] program), or design information from other sites using the same/similar technology and wastes. The data needed may also be chemical in nature, e.g., constituent concentrations in the emissions or discharge, or the chemical identity, toxicity information, quantity, rate of release, and fate and transport characteristics of treatment byproducts, derivatives, or residues.

The CSM should be appropriately modified to help the project team focus the data collection effort to evaluate significant pathways for potential emission or discharge during the remediation period. The CSM focuses on the source, release, fate and transport, and exposure point concentration, routes and receptor to aid the risk assessment.

2.3.4.3 Identify Data Gaps. It should be noted that data needs at this stage of the HTRW project planning should primarily focus on the project decision: "What control measures are required to mitigate the short-term risk to the appropriate human receptors onsite and/or offsite (individuals and community)?" If the RA requires transportation of wastes offsite through areas of dense populations or congested transportation routes, evaluation of controls required to eliminate potential risks of accidents/spills associated with this offsite action may also be required. The risk assessor should coordinate with the health and safety specialist, design engineer, and chemist to define data quality and quantity, and locations of samples.

Guided by the CSM, data may be needed for all or any one of the following risk assessment/evaluation tasks to respond to the project decision on whether or not there is a need to impose control measures; augment or modify the selected remedy; or conduct removal actions:

- Evaluate in more detail the short-term risk assessment/analysis performed for the FS to reduce uncertainties; some of the data requirements may be:
  - Data to support fate and transport modeling/calculation, e.g., grain size of soil handled, residue or solid waste stream leaching characteristics, processed meteorological data, etc.
  - Data to assess the amount of discharge or residues, e.g, amount of soil re-suspension for a specific soil handling method, estimation of fugitive dust volatilization, stack gas emissions, or effluent discharge rates, etc. (i.e., representative monitoring or field data to assess risks and demonstrate compliance with protective criteria/standards are needed).
  - Data to support qualitative assessment of potential exposure to receptors and populations (method of residue disposal or environmental media into which effluents/emissions are discharged, transportation routes for wastes to offsite locations, population or census information, etc.).
  - Data to assess risk or hazard (toxicity information of waste residues, byproducts, derivatives, and degradation products (for bioventing or bioremediation)).
  - Data to compare ARARs and TBC short-term health goals with representative site sample or monitoring data which meet predefined QA/QC criteria.

2.3.4.4 DQOs. This step defines the data types required according to potential exposure pathways. Examples of data types according to medium for use in assessing potential exposure pathways are: incidental ingestion or dermal contact with the treatment residues or effluent and inhalation of airborne particles or volatilized organic chemicals. In each of these data types, sample data or continuous monitoring data, and data for modeling the exposure point concentration for the site contaminants or their treatment derivatives/residues in the media may be needed.

To evaluate the need for control measures for the selected remedial alternatives under this project phase for short-term impact during remediation and residual risk after remediation, data relating to the design, operation, and maintenance of the remediation system are needed to calculate the discharge or release rates of the site constituents and the process waste streams. The process waste streams include chemical characterization of all remediation or treatment byproducts, derivatives, or residues during and after remediation, which may impact onsite and offsite humans. It should be noted that the screening or comparative assessment of remedies for short-term risks should have been conducted in the FS stage, before remedy selection, and in this phase a more rigorous analysis of risks and control measures are developed for the selected alternative. The data quality used in these screening analyses should be reviewed to see if they meet the data user's requirements.

2.3.4.5 Reporting Requirements. The following presents the elements which address different aspects of controls to reduce short-term risks within the design analysis for construction of removal actions or RAs.

- The evaluation of potential control measures necessary to mitigate risks associated with remedial or removal actions; usually part of the design analysis included in the RD.

    - Health and safety design analysis; engineered barriers, monitoring, worker protection, and response measures.

    - Environmental controls and permitting; dust control, air emission control, effluent and runoff controls.

    - Methods of construction; excavation, grading, structure construction, etc. and control features associated with each.

    - Phasing of construction.